DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-755/S-004

Pharmacia & Upjohn Company
Attention: Terry L. Reinstein, R.Ph.
Regulatory Manager, Regulatory Affairs
7000 Portage Road
Kalamazoo, MI 49001

Dear Mr. Reinstein:

Please refer to your supplemental new drug application dated September 9, 1999, received September 14, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Caverject® Injection (alprostadil injection) aqueous.

This "Changes Being Effected" supplemental new drug application provides for a change in the **WARNINGS** section and **Information for the Patient** section of the package insert for the recommended time which should not be exceeded before seeking medical help for prolonged erection following the use of Caverject®.

WARNINGS

> "...The patient must be instructed to immediately report to his prescribing physician, or, if unavailable, to seek immediate medical assistance for any erection that persists longer than ~~6~~ 4 hours."

Information for the Patient:

> "...Accordingly, the patient should be instructed to contact the physician's office immediately, or, if unavailable, to seek immediate medical assistance for any erection that persists longer than ~~6~~ 4 hours."

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted September 9, 1999). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Eufrecina DeGuia, B.S., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Acting Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Daniel A. Shames

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